

Appendix B

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Artificial Intelligence technologies to assist histopathology for prostate cancer diagnosis ID6684

Final scope

Remit and evaluation objective

To appraise the clinical and cost effectiveness of artificial intelligence technologies used to assist [histopathology](#) in the diagnosis of prostate cancer, within their marketing authorisation.

Background

Prostate cancer is the most commonly diagnosed cancer in England, with a 25% increase in cases between 2019 and 2023 ([Prostate Cancer UK, 2025](#)). Each year in the UK more than 64,000 men are diagnosed with prostate cancer and more than 12,000 will die from the disease ([Prostate Cancer UK, 2026](#)). It is estimated that 1 in 6 to 8 men in the UK will get prostate cancer at some point in their lives. Prostate cancer mainly affects men over 50, and risk increases with age ([Prostate Cancer UK 2024](#)) with the most common age of diagnosis at 65 to 69 years of age ([NICE CKS, 2026](#)) This number has increased over the last 10 years, potentially reflecting demographic changes and increased use of Prostate Specific Antigen (PSA) testing ([Cancer Research UK, 2019](#); [National Collaborating Centre for Cancer, 2019](#)). While adenocarcinoma accounts for 95% of prostate cancers, other rare and often more aggressive types exist. These include neuroendocrine tumours (such as small cell carcinoma) transitional cell (urothelial) carcinoma, squamous cell carcinoma and sarcomas, which arise from different cell types in the prostate ([CRUK, 2025](#)).

Presentation and detection of prostate cancer

People with suspected prostate cancer are usually seen within the primary care setting first. While most people with prostate cancer are asymptomatic ([NICE CKS, 2026](#)), symptoms that may cause suspicion of prostate cancer include unexplained:

- lethargy
- lower back or bone pain
- erectile dysfunction
- visible [haematuria](#)
- anorexia/weight loss ([NICE, CKS 2026](#))

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Other symptoms that warrant further assessment include severe or persistent; poor urinary flow and lower urinary tract symptoms such as hesitancy, frequency and [nocturia](#).

Screening for prostate cancer is currently not recommended in the UK ([UKNSC, 2026](#)). Any asymptomatic person aged 50 and over can make an appointment with their GP to discuss testing for prostate cancer ([DoH, 2016](#)). Those groups considered higher risk for prostate cancer, including people with a family history of prostate cancer or people of Black African or Caribbean background are encouraged to discuss with their GP from the age of 45 ([Prostate Cancer UK, 2025](#)). People with inherited genetic mutations (such as BRCA1 or BRCA2) are associated with an increased risk of developing more aggressive prostate cancer. People who were previously treated for prostate cancer and considered in remission typically have their PSA retested at least every 6 months for the first 2 years and if levels remain stable testing usually continues at least once a year ([Macmillan Cancer Support, 2021](#)).

Initial assessment involves PSA testing to provide information on whether specific antigen levels are elevated from normal age-related thresholds. A digital rectal examination (DRE) may be considered to allow assessment of the prostate for signs of prostate cancer. If PSA levels are raised or DRE is abnormal, a referral should be made using the suspected cancer pathway ([NICE CKS, 2026](#)). People with suspected clinically localised prostate cancer should be offered multiparametric MRI (mpMRI) as the first line investigation. This approach aims to improve the detection accuracy of clinically significant cancer and reduce the need for biopsy in those with non-suspicious mpMRIs ([NHSE, Rapid diagnostic pathway, 2022](#)).

The decision on whether to proceed with a prostate biopsy considers this MRI [Likert](#) score alongside PSA density and additional risk factors (such as age, family history and ethnicity) ([GIRFT Urology, 2024](#)). An mpMRI influenced prostate biopsy should be offered to people whose Likert score is 3 or more. Those with score of 1 or 2 should discuss the risks and benefits of a prostate biopsy as part of a shared decision-making ([NICE NG131, 2021](#)).

There is more than one type of prostate biopsy, transrectal ultrasound-guided biopsy (TRUS) and transperineal ultrasound-guided biopsy ([NICE NG131, 2021](#)). GIRFT recommend that local anaesthetic transperineal (LATP) biopsy in an outpatient setting should be the standard approach ([GIRFT, 2024](#)). This is due to the reduced risk of infection in the transperineal biopsy. This approach involves sampling 6 to 8 sites from the prostate using a transperineal route under local anaesthetic ([NICE NG131, 2021](#)). If available, lesions located on mpMRI should be targeted, with a maximum of 4 cores ([GIRFT, 2024](#)). Alternatively, a template biopsy can be carried out under a general anaesthetic which involves taking transperineal core biopsies using a grid system involving systematically sampling across 2 or 3 core sites meaning over 50 core biopsies may be taken. Tissue cores are immediately placed in a preservative (formalin) to “fix” the cellular structure before being transported to the histopathology laboratory.

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Histological pathway

Samples are logged and prepared for processing in paraffin wax blocks. A [microtome](#) is used to slice them into ultra-thin sections which are mounted onto glass slides and stained, typically with Haematoxylin and Eosin (H & E), to make cellular structures visible under a microscope. Prostate cores are particularly thin with a tendency to curve and fragment or both, so additional care must be taken when preparing these tissues ([RCPATH, 2024](#)). Once scanned, these stained histopathology whole slides, referred to as whole slide images (WSIs) are examined microscopically by a consultant histopathologist to look for architectural and cytological abnormalities. If cancer is found the pathologist assigns a [Gleason Score](#) to indicate how aggressive the cells in each gland or cluster appear. An International Society of Urological Pathology ([ISUP](#)) [Grade group](#) classification system is also used to provide more differentiation in intermediate risk categories to support clinical decision-making.

The Royal College of Pathologists have clear published datasets for histopathological reporting on individualised cancers to standardise reporting methods (RCPATH, 2024). For prostate cancer, core items to be reported on include but are not limited to:

- Clinical data (PSA, MRI findings, number and site of prostatic biopsies and type of biopsy)
- Macroscopic pathology data (number of cores or fragments and location)
- Microscopic pathology data (histological type of prostate cancer, number of positive cores per side, longest length of tumour, presence of cribriform, presence of [perineural invasion](#), presence of extra prostatic extension, [Gleason score](#), [Grade group](#), percentage pattern and representative percentage for molecular studies).

If the diagnosis is unclear following initial review the pathology lab may request additional [immunocytochemistry / immunohistochemistry](#) (ICC/IHC) testing. This specialised laboratory technique uses antibodies to identify specific proteins within tissue samples highlighting specific prostate cancer markers.

The reporting times vary significantly depending upon tissue type, case complexity additional testing and referrals for second opinion or on to specialist centres which can increase workload, costs, and lead to diagnostic delays.

[Royal College of Pathologist standards and datasets for reporting cancers](#) state that they expect 80% of cases to be reported, confirmed and authorised within 7 calendar days of the biopsy procedure, and 90% within 10 days. NHS England's best practice timed pathways recommend that men referred with suspected prostate cancer receive the mpMRI and, where indicated, a biopsy within 9 days of GP referral, with pathology results reported within a further 5 days, creating a 14 day turnaround from referral to biopsy result, as reinforced in GIRFT Urology guidance ([2024](#)). More broadly, NHS England's Faster Diagnosis Standard

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(FDS) was introduced to ensure that patients are informed whether they have cancer or cancer is excluded within 28 days of an urgent referral. This standard currently requires providers to meet an 80% threshold as of March 2026 ([FDS, 2022](#)).

Treatment

According to NICE Guidelines ([NG131](#)), treatment decisions should consider tumour characteristics including type, size, grade, and stage as well as PSA level, Gleason score or Grade Group, and imaging findings to determine the individual's risk category and guide shared decision-making. A multidisciplinary team typically reviews each case to ensure that treatment plans reflect both clinical needs, disease severity and individual circumstances including comorbidities and preferences. Options may include active surveillance, radical prostatectomy, or radiotherapy for localised disease, and hormone therapy or chemotherapy for more advanced cancer.

Early diagnosis substantially improves outcomes. Nearly all individuals diagnosed with prostate cancer at the earliest stage survive at least five years, whereas survival drops to around 49% when the disease is diagnosed at the latest stage ([NICE CKS, 2025](#)).

Unmet need

Prostate cancer is the most commonly diagnosed cancer in England ([Prostate Cancer UK, 2025](#)). To expedite cancer diagnoses and improve patient experience, NHS England (NHSE) established the [Faster Diagnosis Framework and Standards](#). However, pathology departments in the country vary in their set up, including differences in subspecialisation for different conditions, digital adoption and use of AI, all of which may contribute to variability in review procedures, review times and the quality of reporting. Additionally the demand for pathology services is growing rapidly, both in volume and complexity, while trained pathologist workforce is shrinking ([RCPath, 2025](#)) putting pressure on service delivery and subsequent patient safety. A [Royal College of Pathologists 2025 workforce census](#) found that 47% of pathologists are aged 50 and over and that 60% of consultant pathologists in the UK are typically working beyond their contracted hours each week. Most pathologists do not believe current staffing levels are adequate to ensure long-term stability of pathology services and to meet growing demand.

In response to workforce shortages, the [Royal College of Pathologists 2025 to 2028 workforce strategy](#) aims to transform current models of working for pathology. This includes developing best practice recommendations on automation, digital and AI to improve the efficacy and efficiency of workflows. The [Royal College of Pathologists position statement on the use of digital pathology and AI](#) supports that there is an increasing body of research and interest in the use of AI for assisting pathologists in diagnosis, and potential to transform working models which could improve healthcare. Key benefits highlighted in this statement include the potential for AI to introduce efficiencies into pathology services by freeing highly trained pathologists from more routine and repetitive work and improve accuracy or consistency in

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pathology diagnosis. A [GIRFT 2025 summary of diagnostics findings and recommendations](#) supported innovation in AI for pathology, and this aligns with the broader [NHS long term plan](#) commitment to introducing AI to increase efficient NHS services, including those committed to faster diagnosis of disease. Standardised reporting using AI may also reduce variability linked to local workforce constraints and support more equitable diagnostic quality across regions.

Digital pathology is a prerequisite to mobilisation of AI-supported histopathology technologies. Adoption of digital pathology is varied but increasing rapidly as a result of the NHS England diagnostics funding. Current adoption data indicates: 25 of 27 pathology networks have begun digital reporting, approximately 80% of acute and specialist trusts are using digital images for primary diagnosis and about 51 trusts are digitally reporting more than 50% of cases.

The technologies

In the histopathology pathway there are a number of AI technologies that propose to improve parts of the workflow. These can include pre-analytical stages, such as quality control and post-analytical stages such as providing heat maps of high-risk areas to support histopathologist review.

Technologies to be appraised in this assessment are those in the post-analytical stage, that use artificial intelligence (AI) to analyse digitised images of tissue samples, called whole slide images (WSI). These technologies propose to assist with a range of tasks that are usually done by one or more consultant histopathologists. Technologies typically provide diagnostic overlays, measurements and prompts for histopathologist reviews to improve accuracy and speed up review times. Uses of the technologies vary driven by differences in technology features and across different pathology laboratory set ups (including use as triage tools, first read and second read). All technologies are intended to support pathologists review and should not be used for final decision-making without pathologist oversight. The technologies aim to support accurate and timely results to assist in diagnosing prostate cancer and support achieving the Faster Diagnosis Standard 28-day target more consistently. Use of the technologies could also reduce inter-observer variability, improve reporting quality standards and consistency across centres, facilitating equitable access across the country.

Technologies included in the scope analyse digitised whole slide images from prostate core needle biopsies that have been stained with H&E. Technologies included in scope should, in line with RCP datasets ([2024](#)), as a minimum;

- detect prostate cancer
- grade the prostate cancer detected, according to Gleason grading
- measure tumour length and proportion of tumour per core
- have appropriate regulatory approval or be in the process of obtaining this and be available to the NHS or be in the process of this.

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Additional features which may be beneficial include detecting [perineural invasion](#), detecting [cribriform](#) patterns, prompting or ordering [immunocytochemistry \(ICC\)](#) or [immunohistochemistry \(IHC\)](#) testing and the ability of the AI technology to support the production of a digitised report using the captured data in a format that can be easily integrated into the histopathologists report.

All technologies identified to be in scope for this assessment are stated in Table 1.

Place of the technologies in the pathway

Technologies should be used in a digital pathology workflow for formalin-fixed paraffin-embedded (FFPE) human prostate core needle biopsy specimens which have been stained with Haematoxylin and Eosin (H&E). Once the slide is ready it is loaded into a digital pathology scanner which uses high-quality optical microscopes to capture the tissue into a whole slide image (WSI) ready for analysis.

The AI technologies in scope support the analysis of the digitised WSI in the detection of prostate cancer. Centres may use these AI technologies in different ways depending on analysis type and individual laboratory practices (for example, as triage, first or second read). The assessment will consider these alternatives if and where appropriate. Some AI technologies may also be used for analysis on resected or excised tissues from the prostate or lymph nodes to understand more about the size, type, stage and grade of cancer to inform management. Costs and effects of technologies in these use cases will not be assessed as part of the scope of this assessment.

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Table 1. Technologies in scope

Technology and Company name	Indication for use of interest	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
<p>Aiforia Clinical Suite for Prostate cancer</p> <p>Aiforia</p>	<p>Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 18 with suspected prostate cancer</p>	<p>Yes</p> <p>Aiforia Prostate Cancer Biopsy module automatically detects prostate cancer</p>	<p>Yes</p> <p>Aiforia Prostate Cancer Biopsy assists in grading using Gleason grading score.</p> <p>Measures lengths of tumour and tissue biopsy to support reporting of disease extent per core.</p>	<p>Yes</p> <p>Aiforia Prostate cancer PNI (perineural invasion) detects perineural invasion from foci of cancer</p> <p>Aiforia Prostate cancer G4 cribriform detects Gleason grade 4 cribriform patterns</p> <p>Aiforia Clinical suite viewer is the software interface used to view the AI analysed images</p> <p>Provides visualisation of the results and manual editing if needed for pathologist oversight and sign off.</p>	<p>Cloud based software as a service platform.</p> <p>Integrates with existing digital pathology systems</p>	<p>All CE-IVDR</p> <p>Aiforia Clinical Suite is MHRA registered and Aiforia Prostate Cancer Biopsy MHRA registration in development</p>	<p>Yes</p>
<p>AIRAProstate</p> <p>AIRA Matrix Private Limited</p>	<p>Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 40 with</p>	<p>Yes</p> <p>AIRA prostate first categorises prostate tissue as either benign or</p>	<p>Yes</p> <p>For tissues identified as suspicious for cancer, the software provides the Gleason grade grouping identified</p>	<p>Yes</p> <p>Detection and quantification of cribriform pattern in grade 4 foci</p> <p>Detection of perineural invasion</p>	<p>Digital software application offering both cloud and on premises solutions that integrate with existing digital</p>	<p>CE-IVD marked</p>	<p>Yes</p>

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Technology and Company name	Indication for use of interest	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
	suspected prostate cancer	suspicious for cancer.	using colour coded overlays. Core length and tumour length measurements	The system presents the analysis as an overlay during the review process. Provides automated report creation	pathology systems.		
DeepDx Prostate Deep Bio	Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 18 with suspected prostate cancer	Yes Detects and localises areas of interest	Yes Using coloured overlays based on Gleason patterns. The proportions of Gleason patterns out of the total tumour area and tumour to tissue ratios are automatically quantified to assist in scoring and automatically measures tissue and tumour lengths.	Yes Deep Bio detects and reports on perineural invasion Identifies cribriform patterns and intraductal carcinoma Measurements can be recalculated in real time as user annotations are made. This can work alongside Deep Dx Viewer to provide multiple image control functions and management features for Deep Dx	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems	CE- IVD marked	Unkno wn
HALO Prostate AI Indica Labs	Indicated for digitised WSIs of prostate tissue from core needle core biopsies of men	Yes Provides cancer detection and localisation	Yes Completes Gleason grading and measurement of tumour size.	Yes Detects and reports on the presence of perineural invasion and intraductal carcinoma	Digital software application offering both cloud and on premises solutions that	CE -IVD marked	Yes

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Technology and Company name	Indication for use of interest	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
	aged over 18 with suspected prostate cancer				integrate with existing digital pathology systems		
<p>Ibex Prostate (formerly known as Galen Prostate)</p> <p>Ibex Medical Analytics</p>	Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 18 with suspected prostate cancer	<p>Yes</p> <p>Detects and highlights suspicious areas of cancer detection on a slide</p>	<p>Yes</p> <p>The software grades cancer, according to Gleason scores</p> <p>Automatically identifies the tissue cores and calculates the tissue and tumour length per core. In addition, it identifies the most involved core and provides the longest length of tumour as a measurement</p>	<p>Yes</p> <p>Detects presence of perineural invasion</p> <p>Detects G4 cribriform patterns</p> <p>Detects high-grade PIN, atrophy and inflammation</p> <p>Can automatically pre order immunohistochemistry (IHC) tests for suspicious or difficult areas</p>	Digital software application offering predominantly cloud as well as on premises solutions that integrate with existing digital pathology systems	CE -IVDR marked	Yes

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Technology and Company name	Indication for use of interest	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
MindPeak Prostate Mindpeak GmbH	Indicated for digitised WSIs of prostate tissue from needle core biopsies of men	Yes Analyses digital histopathology images to pinpoint areas that are suspicious for cancer and grading malignancies to support accurate diagnosis	Yes Analyses the slide and assigns scores based on Gleason patterns Provides precise measurement of tumour volume including overall percentage of tumour present. Calculates maximum tumour length and total tumour area.	Yes Detects perineural invasion and highlights detected instances on the tissue Detects cribriform growth patterns Automatically calculates the ISUP score	Cloud based digital pathology service or dedicated on premise server in the laboratory network.	Regulation in progress. Registration in progress	None
Paige Prostate Suite Tempus (formerly known as Paige.AI)	Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 18 with suspected prostate cancer	Yes Paige prostate detect which identifies and flags areas of interest that are suspicious for adenocarcinoma	Yes Paige prostate grade and quantification evaluates any foci of cancer detected to produce primary and secondary Gleason grade prediction, as well as a percentage and linear measurement of tumour burden.	Yes Paige prostate perineural invasion identifies the presence or absence of perineural invasion (PNI) in the images and uses a slide overlay to indicate predicted locations of the focus of cancer more likely to harbour PNI. Detection and reporting on cribriform patterns.	Software based AI system which can be deployed either as a cloud-based platform or directly within a hospitals IT infrastructure	CE IVDR marked	Yes

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Technology and Company name	Indication for use of interest	Detection	Grading and measurements	Additional features (including PNI)	Infrastructure	Regulation	NHS use
Qai Prostate Grade Qrtive	Indicated for digitised WSIs of prostate tissue from core needle biopsies of men aged over 18 with suspected prostate cancer	Yes Provides automated analysis within Pantheon digital pathology platform by identifying prostate cancer and classifying into benign and malignant areas	Yes Completes Gleason grading, ISUP grade, digitally calculated metrics and annotations on the WSI. Quantitative summaries of tumour size and percentage for each tissue	Yes Provides automated report creation	Digital software application offering both cloud and on premises solutions that integrate with existing digital pathology systems	Not currently UKCA or CE marked	Unknown

Decision Problem

Interventions	<p>AI technologies that assist histopathology review of whole slide images of core needle prostate biopsies for the initial diagnosis of prostate cancer. These are proposed to include:</p> <ul style="list-style-type: none"> • Aiforia Clinical Suite for Prostate Cancer (Aiforia) • AIRA Prostate (AIRA Matrix) • Deep Dx (Deep Bio) • HALO Prostate AI (Indica Labs) • Ibex Prostate (Ibex Medical Analytics) • Mindpeak Prostate (Mindpeak GmbH) • Paige Prostate (Tempus) • Qai prostate Grade (Qritive)
Population	Adults who have undergone a core needle biopsy for suspected prostate cancer and are awaiting initial diagnosis
Subgroups	People who have had treatment (chemotherapy, radiotherapy or androgen deprivation therapy) for a previous prostate cancer episode which was considered in remission.
Comparators	<p>Histopathologist review of prostate biopsies without the use of AI</p> <p>Reference standard for test accuracy will be determined by the evidence</p>
Outcomes	<p>The outcome measures to be considered include:</p> <p>Intermediate outcomes:</p> <ul style="list-style-type: none"> • diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value) • case review time / turnaround time [slide review time, number of cases reviewed per session, time to produce report for the multidisciplinary team meeting (MDT)] • time to diagnosis (referral to diagnosis, biopsy to MDT) • time to initiate treatment (referral to diagnosis, referral to treatment, MDT to treatment) • concordance between AI and pathologist review • need for / use of additional tests (repeat biopsies / rescans, immunochemistry) • need for second pathologist read

	<ul style="list-style-type: none"> • effect of acquisition methods on accuracy • proportion of slides not appropriate for AI review and reason for it • adverse events or technical failure • feature level accuracy • impact on clinical decision-making <p>Clinical outcomes</p> <ul style="list-style-type: none"> • grade of cancer at detection • overall survival • prostate cancer specific mortality • metastasis-free survival, progression free survival, distant disease-free survival • adverse effects of treatment, including under or overtreatment <p>Patient reported outcomes</p> <ul style="list-style-type: none"> • health-related quality of life • service user and carer acceptability, views and experience <p>Other</p> <ul style="list-style-type: none"> • user ease of use or user acceptability <p>Resource use</p> <ul style="list-style-type: none"> • cost of technology, considering <ul style="list-style-type: none"> ○ procurement ○ implementation ○ ongoing running costs ○ IT set up ○ costs of updates ○ costs of data storage ○ cost of training • costs of second reads • costs of repeat interventions (for e.g. scans, biopsies) • costs of additional tests (for e.g. IHCs) • cost of managing cancer, related to missed cancers or overdiagnosis
Setting	NHS histopathology services for prostate cancer diagnosis

<p>Economic analysis</p>	<p>The NICE reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.</p>
<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the CE marking.</p> <p>Digital infrastructure: Infrastructure supporting digital pathology is a pre-requisite of the use of AI for histopathology. In line with national priorities for diagnostic and cancer services, centralised investment and rollout is supporting uptake of digital pathology, nationally. The level of digital adoption underpins the implementation of AI technologies included in the assessment. NHS IT and laboratory information management system compatibility and capacity issues may be a potential barrier to the implementation of AI software. Clinical pathways for these technologies vary across the devolved nations.</p> <p>Data security is essential when deploying AI technologies for histopathology as they require access to patient data. There may be challenges around storage and infrastructure requirements, confidentiality, integrity, and governance of data stored. Consideration should be made to issues such as data ownership and custodianship, risks of re-identification of depersonalised data, unauthorised access and system vulnerabilities, and consent and data sharing. Key to these concerns is the location of data storage and processing (e.g., on-site or cloud-based), and the security measures employed.</p> <p>Equity of access There is significant variation in histopathology laboratories across the countries due to differences in setup, workload, workforce capacity and the rate of digital adoption.</p> <p>If AI technologies can improve review turnaround times and the quality of diagnostic accuracy reporting as they propose, this could help reduce variability across pathology labs and local workforce constraints, improving equity of access to</p>

	<p>timely diagnosis and management.</p> <p>Technology validity for the assessment population The validity of AI algorithms depends on the data on which it is trained. When available, information will be reported on the representativeness of training and validation datasets for adults who have had core needle prostate cancer. If groups are not represented, the assessment will consider the potential to exacerbate or introduce health inequalities.</p> <p>These technologies may offer additional benefits for people with low-risk prostate cancer. The proposed improved accuracy and consistency in reporting across labs may further inform decision-making for clinical management of low-risk prostate cancer, potentially reducing overtreatment.</p> <p>Quality assurance Caution is raised that cases with significant artefacts may reduce performance and interpretation of technologies. The quality of reporting for AI assisted biopsies should be audited as part of laboratory practice (RCPath, 2024). Performance monitoring and post-deployment validation is necessary to ensure diagnostic performance remains consistent across institutions and patient populations.</p> <p>AI acceptability and implementation: Work by the Academy of Medical Sciences suggests that patients strongly support the use of AI in healthcare provided it improves quality and frees up time. The Royal College of Pathologists advise there is a need for more engagement with patients about the potential use of AI in their healthcare in order to maintain broad public support (RCPath, 2024). Confidence in the data informing the AI being representative is an important consideration in public acceptance of these technologies.</p> <p>From a user perspective, optimal integration with existing workflows is key to both successful deployment and accessing the benefits of AI in pathology lab workflows. The benefits seen from adoption of AI technologies may vary depending on the pathology lab set up considering the scale of the pathology lab, accreditation of the laboratory, sub specialities training in the lab, integration and compatibility with existing digital pathology infrastructure and use of the technology as triage tool, first or second reads.</p> <p>AI technologies are intended to be assistive so transparency and explainability of AI outputs may be a desirable feature.</p> <p>Technologies vary as to whether they offer on-site or cloud-based deployment options, or both. Flexibility may facilitate uptake and implementation in smaller district general hospitals.</p>
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	<p>Training: Workforce training is required for the safe and optimal use of AI technologies in this pathway. Most technologies report to provide training delivery packages online alongside user guides, support services which should be used in conjunction with local competency sign offs.</p> <p>Existing histopathology training programmes are on glass slide reviews and do not include review of WSI using digital pathology.</p> <p>The benefits of AI may differ depending on histopathologist experience, which will be considered where appropriate.</p> <p>Sustainability: AI assisted workflows claim to increase efficiency and reduce waste associated with physical lab processes.</p>
<p>Equality considerations</p>	<p>No equality issues were identified. Equality considerations include:</p> <p>Usability: Accessibility and compatibility of technologies with assistive technologies for users with disabilities affecting vision or digital interaction should be considered.</p> <p>Health inequality issues and equality considerations are reported in the equality and health inequality impact assessment.</p>
<p>Related NICE recommendations</p>	<p>Related Health Tech Guidance:</p> <p>Transperineal biopsy for diagnosing prostate cancer (2023) NICE HealthTech guidance 680</p> <p>MRI fusion biopsy systems for diagnosing prostate cancer (2023) NICE HealthTech guidance 678</p> <p>Paige Prostate for prostate cancer (2021) Medtech innovation briefing, MIB280.</p> <p>Related Health Tech Guidance in development:</p> <p>Artificial intelligence technologies to help detect prostate cancer on multiparametric (mp) MRI. NICE Guidance. Publication date to be confirmed.</p> <p>Related technology appraisals:</p> <p>There are 24 published technology appraisals on prostate cancer and 4 in development.</p> <p>Related NICE guidelines:</p>

	<p>NICE's guideline on prostate cancer: diagnosis and management (2021) NICE guideline NG131</p> <p>Related NICE guidelines in development:</p> <p>Prostate cancer: diagnosis and management (update) NICE guideline. Publication TBC</p> <p>Suspected Cancer: recognition and referral (update). NICE guideline. Publication expected March 2026</p> <p>Related quality standards:</p> <p>Suspected cancer (2016) Quality standard 124 Last updated: 05 December 2017</p> <p>Prostate Cancer (2015) Quality standard 12 Last updated: 30 December 2021</p>
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Glossary of terms

Biopsy

A sample of tissue from the body to assist in diagnosis of disease

Cribriform

The presence of a cribriform growth is a specific morphological pattern seen in microscopic review of core biopsies. It is recognised as a specific high risk growth pattern. All Cribriform patterns, regardless of size, are classified as Gleason pattern 4. Presence of invasive cribriform or intraductal carcinoma is a core data requirement for microscopic review of prostate core biopsies.

Gleason Grading

The Gleason grading is a method used by pathologists to determine the aggressiveness of prostate cancer by examining its microscopic pattern, ranging from 1 (normal-looking) to grade 5 (very abnormal). The higher grades mean the cancer is more likely to grow and spread outside of the prostate.

Gleason scoring

There may be more than one grade of cancer in the biopsy samples. A Gleason score is worked out by adding together two Gleason grades using, the most common grade and the highest other grade in the samples. For those with detected prostate cancer, scores will be between 6 and 10.

Haematuria

Is the presence of red blood cells in the urine. It is categorised as either visible where urine appears pink, red or brown or non-visible, where blood is detected only via laboratory testing or urine dipstick. It indicates bleeding in the urinary tract and requires investigation.

Histopathology

The microscopic examination of biological tissues to study, diagnose, and understand the manifestations of disease.

Immunohistochemistry (IHC) and Immunocytochemistry (ICC) testing

These are specialised laboratory techniques used to detect specific proteins in samples. IHC studies intact tissue sections and ICC studies individual cells both identifying specific prostate cancer markers.

ISUP score (grade group)

International Society of Urological Pathway score, is a 5-tier grading system to provide a more accurate and standardised assessment of prostate cancer severity.

Likert score

This radiologist reported scale assesses the probability of clinically significant

prostate cancer on a multi-parametric MRI. It represents a subjective assessment, often incorporating factors like PSA density and clinical history

Microtome

Is a specialised precision cutting instrument used in laboratories to slice materials, typically embedded biological tissue, into extremely thin sections for microscopic examination

Nocturia

Is the term for waking up one or more times during the night to urinate, often disrupting sleep

Perineural invasion

Is a pathological finding where cancer cells are seen surrounding and tracking along or invading the nerve sheath within the prostate gland. It is reported when malignant cells surround at least one third of a nerve's circumference.